6752. Barium sulfate. (F.D.C. No. 46418. S. No. 96–443 R.)

QUANTITY: 2,843 10-lb. cans, at Vineland, N.J., in possession of Eastern Laboratories, Inc.

SHIPPED: 5–17–61, from New York, N.Y.

LABEL IN PART: (Can) "Barium Sulfate U.S.P. * * * Eastern Laboratories, Inc. * * * Whittaker, Clark & Daniels, Inc. New York, New York."

RESULTS OF INVESTIGATION: Analysis showed that the article failed to conform to the United States Pharmacopeia requirements for *barium sulfate*, in that it did not meet the limits for acid-soluble substances, soluble barium salts, and sulfide, when tested in accordance with U.S.P. XVI.

The article had been repacked and labeled as described by the dealer from bulk stock shipped as "Lot #333 Blanc Fixe."

LIBELED: 8–29–61, Dist. N.J.

CHARGE: 501(b)—while held for sale, the article purported to be and was represented as a drug, barium sulfate, the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality fell below the standard set forth in such compendium; and 502(a)—the article's label statement "Barium Sulfate U.S.P." was false and misleading as applied to a product which did not conform to the standards for *barium sulfate*, U.S.P.

DISPOSITION: 10–23–61. Consent—claimed by the dealer and released under bond for relabeling.

6753. Pas-C tablets. (F.D.C. No. 46526. S. No. 13–747 T.)

QUANTITY: 33 1,000-tablet btls. at Milwaukee, Wis.

SHIPPED: 10–2–61, from Chicago, Ill., by Hellwig, Inc.

LABEL IN PART: "Hellwig Pas-C Pascorbic 0.5 Grams Conjugated Para-Amino Salicylic Ascorbate Hellwig, Inc."

RESULTS OF INVESTIGATION: Analysis showed that the article was para-aminosalicylic acid. No ascorbic acid was found.

LIBELED: 11–7–61, E. Dist. Wis.

CHARGE: 501(d)(2)—when shipped, para-aminosalicylic acid had been substituted in whole or in part for conjugated para-aminosalicylic ascorbate; and 502(a)—the label statement "Conjugated Para-Amino Salicylic Ascorbate" was false and misleading when applied to an article which contained no ascorbate but was entirely para-aminosalicylic acid.

DISPOSITION: 12–4–61. Consent—claimed by Hellwig, Inc., without admitting the allegations of adulteration and misbranding, and released under bond for relabeling.

6754. Isoproterenol hydrochloride sublingual tablets. (F.D.C. No. 46342. S. No. 30–801 T.)

QUANTITY: 190 50-tablet btls. at Los Angeles, Calif.

SHIPPED: 6–25–61, from Philadelphia, Pa., by Physicians' Drug & Supply Co.

LABEL IN PART: "50 Sublingual Tablets Isoproternol Hydrochloride U.S.P. Each tablet contains: Isopropylarterenol HCl U.S.P. 15 mg. * * * Physicians' Drug & Supply Co. Philadelphia 6, Pa."

RESULTS OF INVESTIGATION: Analysis showed that the article failed to conform to the United States Pharmacopeia requirement for sublingual tablets in that it failed to disintegrate within three minutes as specified in U.S.P. XVI.

LIBELED: 9–25–61, S. Dist. Calif.

CHARGE: 501(b)—when shipped, the article purported to be and was represented as isoproterenol hydrochloride tablets, a drug, the name of which was recognized in the United States Pharmacopeia, an official compendium, and its quality differed from the U.S.P. standard for isoproterenol hydrochloride tablets; and 502(a)—the label statement "Isoproternol Hydrochloride U.S.P." was false and misleading as applied to this product which failed to conform to the U.S.P. standard for isoproterenol hydrochloride.

DISPOSITION: 10–19–61. Default—destruction.

6755. L.G.B. 12–100. (F.D.C. No. 45638. S. No. 29–800 R.)

QUANTITY: 14 individually ctnd. 10-cc. vials at Minneapolis, Minn.

SHIPPED: 12–5–60, from Decatur, Ill., by Taylor Pharmacal Co.

LABEL IN PART: (Ctn. and vial) "L.G.B. 12–100 10 cc. For Intramuscular injection Cat. No. 2185 Each cc. contains Vitamin B_{12} Activity (From Liver Injection U.S.P. Beef) Equivalent to: Cyanocobalamin 10 Mcg. * * * Vit. B_{12} Cryst 100 Mcg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 70 percent of the declared amount of vitamin B_{12}.

LIBELED: 4–25–61, Dist. Minn.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statement "Each cc. contains Vitamin B_{12} Activity (From Liver Injection U.S.P. Beef) Equivalent to: Cyanocobalamin 10 Mcg. * * * Vit. B_{12} Cryst 100 Mcg." was false and misleading.

DISPOSITION: 6–29–61. Default—destruction.

6756. Sulfacetamide. (F.D.C. No. 45808. S. No. 17–095 R.)

QUANTITY: 1 100-lb. drum at Indianapolis, Ind.

SHIPPED: 1–16–61, from New York, N.Y.

RESULTS OF INVESTIGATION: Analysis showed that the article had a melting point of 140 degrees centigrade to 184 degrees centigrade (the National Formulary requires a melting point of 181 degrees centigrade to 184 degrees centigrade), and that the article contained an appreciable amount of sulfanilamide.

LIBELED: 6–6–61, S. Dist. Ind.; amended libel 6–15–61.

CHARGE: 501(b)—while held for sale, it was found that the article purported to be and was represented as a drug, sulfacetamide, the name of which is recognized in the National Formulary, an official compendium, and its strength, quality, and purity differed from the standard set forth in such compendium; and 501(d)(2)—it was found that sulfanilamide had been substituted in part for sulfacetamide.

DISPOSITION: 9–5–61. Default—destruction.

6757. Imitation drugs. (F.D.C. No. 45770. S. Nos. 1–857 R, 58–111/12 R.)

QUANTITY: 1 btl. containing approximately 400 tablets, and 1 btl. containing approximately 1,000 tablets consisting in part of *imitation Serpasil Tablets;* and 1 btl. containing approximately 80 tablets consisting of *imitation Equanil tablets*, at Athens, Ga., in possession of Crow's Drug Store, Inc.

SHIPPED: During 1958 and on 1–15–59, from Houston, Tex.